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Atty. Dkt. No. 078728-0106

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Joseph ROBERTS *et al.*

Title: **CLONING, OVEREXPRESSION AND THERAPEUTIC USE OF BIOACTIVE HISTIDINE AMMONIA LYASE**

Appl. No.: 09/833,745 Filed: 4/13/01

Examiner: Charles L. Patterson, Jr. Art Unit: 1645

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Box NON-FEE AMENDMENT
Washington, D.C. 20231

Sir:

In response to the restriction requirement set forth in the Office Action mailed July 30, 2002, Applicants elect Claims 7-20 (Group VII), with traverse.

If additional extensions of time are necessary to prevent abandonment of this application, then extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required, including fees for net addition of claims, are hereby authorized to be charged to account number 19-0741.

The Examiner has asserted that the original claim set should be restricted to one of the following, allegedly distinct groups: I. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 1); II. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 2); III. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 3); IV. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 4); V. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 5); VI. Claims 1-6 (drawn to a polypeptide comprising SEQ ID NO: 6); VII. Claims 7-20 (drawn to a method of treatment comprising administering a lyase and a method for delivering an immunosuppressant to a patient); VIII. Claims 21 and 22 (drawn to a DNA and a vector); and IX. Claim 23 (drawn to a method for treating a patient comprising introducing an expression vector into the patient). Applicants respectfully disagree.

To substantiate the proposition that "the inventions [recited in the different groupings] are distinct, each from the other," the Examiner argues that the polypeptides of groups I-VI are "structurally different" (office action, page 2). However, the respective claims of groups I –VI all recite polypeptides that possess similar chemical properties because the polypeptides have in common the sequence of SEQ ID No. 1, which is the amino acid sequence of the active site of the histidine ammonia lyase enzyme. That is, SEQ ID Nos. 2-5 are expanded regions that encompass the active site of SEQ ID NO:1, with SEQ ID No. 5 delineating the entire peptide sequence of the histidine ammonia lyase enzyme. Accordingly, SEQ. ID NOs. 2-5 all are subsets of SEQ ID NO. 1. SEQ. ID No. 6 likewise comprises SEQ ID No. 1and highlights sequence variations the invention contemplates.

The Examiner also states that although Groups I-VI and VII are related as product and process of use, groups I-IX are unrelated because "the product as claimed can be used in a materially different process such as for its enzymatic activity not related to treatment." (File Wrapper Paper No. 9, page 3). Restriction is proper when the products *as claimed* can be used in *materially* different processes. It is enzymatic activity of the polypeptide that makes it an effective therapeutic; hence, the therapeutic capability of the polypeptide, as the DNA encoding the polypeptide, cannot be divorced from the enzyme's activity, as the examiner states.

To sustain a proper requirement for restriction, the Examiner must demonstrate that the independent and distinct inventions meet two criteria. First, the inventions *must* be independent or distinct as claimed, and second, there *must* be a serious burden on the Examiner. Applicants submit that the Examiner has not fulfilled even one of these requirements.

The Examiner further states that the inventions are distinct because the searches are not co-extensive. However, "[s]eparate status of the art may be shown by citing patents which are evidence of such separate status [of the inventions], and also of a separate field of search" (MPEP, 8th Ed., § 808.02). In the current restriction requirement, the Examiner has not demonstrated by "appropriate explanation" that each subject has attained a separate status in the art by citing patents in support of this contention. (MPEP,

8th Ed., § 803). Furthermore, the Examiner's own restriction and classification highlights that Groups I-VI fall into one class (435) and one subclass (232). Groups VII and VIII also fall into the same class (435). Thus, the Examiner himself has demonstrated that the searches can be co-extensive and that the identified groups have not achieved a separate status on the art.

At a minimum, Groups I-VII should be rejoined because examining them would involve searching only one class and two subclasses, which should not be considered a "serious burden." The Examiner is reminded that, "[i]f the search and examination of the entire application can be made *without serious burden*, [then] the examiner *must* examine on the merits, even though it includes claims to independent or distinct inventions." MPEP §803 (8th ed.) (emphasis added).

In summary, the Examiner has not demonstrated that there would be a serious burden if restriction is not required. Furthermore, the Examiner has not provided any evidence that the inventions are independent and distinct, or that no relationship exists between the disclosed subjects (MPEP, § 802.01). Accordingly, the restriction requirement is improper and should be withdrawn. At a minimum, Groups I-VII should be rejoined.

Applicants await an action on the merits. In the meantime, should the Examiner believe that further discussion of any issues would advance the prosecution, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date 29 August 2002

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